REMARKS/ARGUMENTS

Claims 7, 10, 12, and 13 have been amended. Therefore, claims 1-13 remain pending in the application.

I. Amendments to the Specification

The Office indicated that the abstract was not in compliance with the 150-word maximum. Therefore, the abstract has been amended, and a replacement abstract is attached to the end of this paper for inclusion in the application.

II. Amendments to the Claims

A. Rejections under 35 U.S.C. § 112, second paragraph

The Office rejected claims 7-12 as being indefinite based on the term "RDBMS" in claims 7 and 10 lacking proper antecedent basis. In response, claims 7, 10, and 13 have been amended to replace the term "RDBMS" with "database management system." Therefore, it is respectfully requested that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

B. Rejections under 35 U.S.C. § 101

The Office rejected claims 7-12 as being directed to non-statutory subject matter. The basis for the rejection was that claim 7 recited "software" per se, and that such claim did not indicate the use of hardware on which the software runs to perform the steps recited in the body of the claim. In response, claim 7 has been amended to clarify that the software resides on a computer server as it communicates with the database management system. Therefore, it is respectfully requested that the rejections under 35 U.S.C. § 101 be withdrawn.

C. Rejections under 35 U.S.C. § 102

Claims 1-13 were rejected under 35 U.S.C. § 102(a) as being anticipated by the article co-authored by Monique Calisti (hereinafter "Calisti"). The Office indicates in its Notice of References Cited (PTO-892) that the Calisti article was published in September 2003, which is roughly one month prior to the effective filing date of the present application.

1. The present invention was made prior to the Calisti publication.

In response to the rejection, the applicants submit herewith a declaration under 37 C.F.R §1.131 by Kelly Ranum, one of the inventors and director of the Louisiana Organ Procurement Agency (LOPA) (the "Ranum declaration"). As the declaration indicates, the invention of the claims in this application was reduced to practice many months prior to the publication date of the Calisti reference. Ms. Ranum further attests that dated hard-copy and electronic evidence exists to support her statements, and that the attachments to the declaration are true and correct copies of the materials that constitute that evidence. The first material, marked Exhibit 1, is one of the PowerPoint presentations that was made to the organ procurement association field, this presentation having been given on March 20, 2003, to the SEOPF Information Technology Seminar in Atlanta, Georgia, by Kathy Pizzolato (one of the co-inventors). That presentation includes screenshots of the actual "Referrals, Reports, and Resources" web-based software application, also referred to as the R3 system, owned by LOPA. Ms. Ranum further attests that at the time of that presentation in March 2003, the R3 system was already in its third version, version 1.2.

Also attached to the Ranum declaration and attested to by Ms. Ranum is a copy of an early draft of the R3 System Documentation prepared by the Johnston & McLamb software developers, particularly Mo Shah (one of the co-inventors). The draft is dated February 3, 2003, and its contents on page 5 further indicate that the initial draft was created December 20, 2002. This system documentation demonstrates that several months prior to publication of the Calisti article, the R3 System was reduced to practicc and implemented and that extensive documentation had been prepared detailing the workings of the system.

Based upon the Ranum declaration and the evidence submitted therewith, it is clear that long before the September 2003 publication of the Calisti article, not only was the claimed invention reduced to practice, but the software embodying the claimed invention was also fully operational and in production use at LOPA. In summary, the timeline of these materials is as follows:

December 20, 2002 – R3 System documentation created

February 3, 2003 – R3 System Documentation updated

March 20, 2003 – Presentation of R3 System in detail on Power Point at industry meeting

September 2003 - Calisti article published

Therefore, it is respectfully requested that the rejections under 35 U.S.C. § 102(a) be withdrawn on the basis that the present invention was conceived and reduced to practiced before the cited reference.

2. Calisti publication would not anticipate the present invention.

Even disregarding the fact that the present invention pre-dates the effective date for the Calisti article, that reference would fail to anticipate the claimed invention under §102 and would fail to establish a prima facie case for obviousness under §103.

From a detailed reading of the Calisti article, it is apparent that the concepts discussed are related to an artificial intelligence (AI) system related to organ transplant management. At the time that article was published, the proposed system was in the developmental or even conjectural stages. As such, the article identifies few concrete details about the architecture of components and the information flow that would be required in order to assess whether elements of the claimed invention are met. For example, page 200, Section 1, includes the following statement by the authors:

> "This paper describes the OTM system aiming at identifying the main challenges and benefits that our agent-based approach brings along to validate and/or eventually modify our choices. This hopes to stimulate discussion and provide feedback on the feasibility and utility of deploying software agents in today's medical environments."

With regard to the claims, Claim 1 defines an organ and tissue procurement system, comprising the following elements:

> "...interface server means for storing and delivering user interface information accessible to authorized users over a wide area network;
>
> database server means, in communication with said interface server means, for storing and delivering data related to donors and recipients of human organs and tissue; and
>
> software means, in communication with said interface server means and said database server means, for enabling access to said data and said user interface information by said authorized users, wherein said software means includes:
>
> (a) security means for determining whether one or more of said authorized users may modify said data; and
>
> (b) import means for receiving donor information from at least one external database and adding said donor information to said data."

In contrast, Calisti proceeds to discuss a number of components or modules of the theorized system, e.g. Kerberos ID-type security, personalized user interfaces, notification priorities, but does not describe the use through human interaction of the interface server means for access to a wide-area network in conjunction with the database server thereby rendered accessible to multiple points on the system simultaneously and the software server that imports donor information from an external data base and adds it to the overall managed and organized data. The Calisti article also introduces a "match-making" module which the claimed invention lacks and does not implement as a regulatory and ethical matter. Calisti describes the AI behind the choices she and her colleagues made in setting parameters for such matching. Calisti's field of expertise is AI, and her efforts envision the expansion of AI concepts and structure to traditional fields of human judgment, such as the medical arts. The use of AI in OTM is seen by Calisti as a potential application where decisions by computers can replace human agents' judgment, because she apparently believes (though does not explain how) the data can be circumscribed and complete enough to allow computerized matching according to set parameters and appropriate oncology. The R3 System, however, does not turn the judgment on matching over to computers. Moreover, Calisti's model is based in Switzerland, not in this country where abdication of the judgment process for organ and recipient matching would not be allowed in light of UNOS requirements, guidelines and ethical constraints. Notably, the article appears to invite dialog on whether the authors have "gotten it right", seeking feedback on whether they are covering the kinds of information organ transplant professionals need, and whether their terminology is useful. The authors also express concern for whether their "ontology" is compliant with other medical databases. However, they have not stated with any detail how the system is actually constructed or "wired" or shown that it will achieve specific results.

With respect to claim 7, that claim (as amended) defines an organ and tissue procurement system, comprising the following elements:

> "...software means residing on a computer server for communicating with a database management system corresponding to and operating upon one or more databases and configured to create links between select fields of said databases;
>
> wherein said one or more databases are configured to store medical and social history information about a plurality of prospective donors under conditions that would allow salvage of tissue or organs from said prospective donors ("donor data"), and medical and social history information about a plurality of prospective recipients ("recipient data");

> wherein said database management system is configured to access said one or more databases and to determine whether said donor data is stored in said one or more databases; and
>
> wherein said database management system is further configured to access said one or more databases to determine whether any of said donor data corresponds to any of said recipient data sufficient to establish a preliminary match between said donor data and said recipient data."

Again, Calisti fails to disclose sufficient details of a software and hardware system capable of communicating with the database management system which operates on databases having donor data and recipient data. It also fails to teach how such donor data and recipient data are used to determine a "preliminary match" between a donor and a prospective recipient. The same argument can be made with respect to the method of claim 13.

Finally, Section 5 of the Calisti article makes it clear that their OTM model requires various refinements and "extensive validation and testing in the field". A number of areas are specifically described as requiring further work or improvement, and that close collaboration with medical professionals is still needed to better define various components, particularly in the match-making module.

In order for the Calisti article to operate as a valid reference, that reference must be enabling to a person of ordinary skill in the art to which the invention pertains. However, it is clear that no person, however skilled they may be in software development, artificial intelligence, or otherwise, would be capable of producing the proposed Calisti system without an enormous amount of "undue experimentation" and the additional work described by the authors themselves. Most of the information presented in Calisti relates to overall data modeling rather than actual implementation of a software system which accomplishes specific computational and organizational tasks. This is to be contrasted with the claimed invention, as operated by LOPA, which has been in successful production use since the end of 2002.

Therefore, even if Calisti were a proper reference from the standpoint of its effective date, it would not be sufficient to anticipate the specific elements of the claims, nor would it serve to render the claims as obvious to a person of ordinary skill in this field. Consequently, the applicants respectfully request that any rejections based on the Calisti reference be withdrawn.

III. Conclusion

For the reasons expressed herein, the applicant respectfully requests that a Notice of Allowance be issued in this case. If the Office believes that there remain any impediments to such a Notice of Allowance, the undersigned would welcome a telephone call to resolve such issues as quickly as possible.

Respectfully submitted:

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